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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,417	11/24/2003	Kun-Liang Guan	UM-08469	5108
<div>7590 06/01/2007 David A. Casimir MELDEN & CARROLL, LLP Suite 350 101 Howard Street San Francisco, CA 94105</div>			<div>EXAMINER WOOD, AMANDA P</div>	
			<div>ART UNIT 1657</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE 06/01/2007</div>	<div>DELIVERY MODE PAPER</div>

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/720,417	Applicant(s) GUAN, KUN-LIANG	
	Examiner Amanda P. Wood	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-45, 47 and 49 is/are pending in the application.
- 4a) Of the above claim(s) 36-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34, 35, 45, 47 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response and amendments filed 6 March 2007 have been received and entered.

Currently, claims 34-45, 47, and 49 are pending.

Claims 36-44 have been withdrawn as being drawn to non-elected species.

Claims 34, 35, 45, 47, and 49 are presented for consideration on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34, 35, 45, 47, and 49 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for rapamycin, does not reasonably provide enablement for all mTOR inhibitors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In particular, Applicant only provides evidence showing that rapamycin may be used to inhibit mTOR, but does not provide any other evidence showing that Applicant had possession of any other inhibitors of mTOR, or what types of other agents may be used to inhibit mTOR. Therefore, claim 34 is deemed not enabled due to its broad scope with respect to the limitation "mTOR inhibitor," because an undue amount of experimentation would be required for one of ordinary skill in the art to practice the instant invention as claimed.

Claims 34, 35, 45, 47, and 49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 34 (lines 1,4, and 5) contain the phrase "type II diabetes mellitus" or "type II diabetes." There is insufficient support for these phrases in the instant specification. Accordingly, these phrases are deemed new matter.

Claim 47 (lines 1-2) contains the phrase "said type II diabetes mellitus comprises complications associated with type 2 diabetes mellitus." In addition, Claim 49 (lines 1-2) contains the phrase "wherein complications associated with type 2 diabetes mellitus comprise renal dysfunction." There is insufficient support for the disease "type 2 diabetes mellitus" in the instant specification, and in addition, there is insufficient support for "complications associated with type II diabetes mellitus" or complications comprising "renal dysfunction" in the instant specification. Accordingly, these phrases are deemed new matter.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, first paragraph for the reasons set forth above.

Response to Arguments

Applicant's arguments filed 6 March 2007 have been fully considered but they are not persuasive. The Examiner notes that Applicant voluntarily changed the election of "type I diabetes" to "type II diabetes" in the Supplemental Amendment and Response filed 11 August 2006. The Examiner also notes that in a telephone call from Applicant's representative on 10 August 2006 to the Examiner, Applicant was merely given permission by the Examiner to submit a supplemental response to the Restriction Requirement of 26 May 2006, prior to the Examiner's first office action on the merits of the case. The election of a species for examination does not inherently provide support or enablement of that species for purposes of 35 U.S.C. 112.

Applicant's argument that the instant Specification supports "type II diabetes mellitus" is not found persuasive. In particular, Applicant argues that one of ordinary skill in the art, upon reviewing the instant Specification, would recognize that Applicant is referring to type II diabetes mellitus when discussing diseases or conditions which have aberrant regulation of cellular energy levels. Applicant argues that such conditions include type II diabetes. Applicant's argument is not found persuasive, however, because any number of diseases could be described as having aberrant regulation of cellular energy levels, cellular energy imbalances, increased cellular energy, etc. Applicant does not specify anywhere in the instant specification that type II diabetes is one such disease that Applicant wishes to claim, nor does Applicant describe diseases comprising cells having increased cellular energy, increased mTOR function, or increased phosphorylated-S6K as type II diabetes mellitus.

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Conclusion

No Claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda P. Wood whose telephone number is (571) 272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

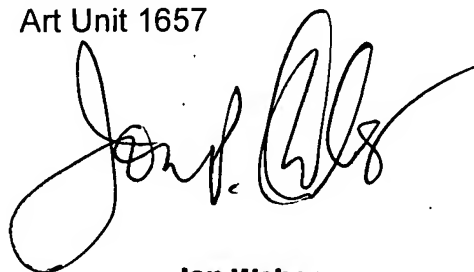
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

APW

APW
Examiner
Art Unit 1657

A handwritten signature in black ink, appearing to read 'Jon Weber', with a large, stylized loop at the end.

Jon Weber
Supervisory Patent Examiner